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ENVIRONMENTAL PROTECTION

ENVIRONMENTAL REGULATION

DIVISION OF ENVIRONMENTAL SAFETY AND HEALTH

Regulations Governing the Certification of Laboratories and Environmental Measurements

Proposed Readoption: **N.J.A.C. 7:18**

Authorized by: Lisa P. Jackson, Commissioner
Department of Environmental Protection

Authority: N.J.S.A. 58:12A-1 et seq.; 58:10A-1 et seq.;
26:2D-70 et seq.; 13:1E-1 et seq.; 13:1K-6
et seq.; 58:10-23.11 et seq.; 26:2C-1 et seq.;
and 13:1D-9 et seq.

Calendar Reference: See summary below for explanation of the
exception to the calendar requirement.

DEP Docket No.:

Proposal Number: PRN 2006-

Submit written comments by (60 days after publication) to:

Oneida Cuevas, Esq.
Attention: DEP Docket No. _____
Office of Legal Affairs
Department of Environmental Protection
P.O. Box 402
Trenton, New Jersey 08625-0402

The Department of Environmental Protection (Department) requests that commenters submit comments on disk or CD as well as on paper. Submission of a disk or CD is not a requirement. The Department prefers Microsoft Word 6.0 or above. Macintosh™ formats

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should not be used. Each comment should be identified by the applicable N.J.A.C. citation, with the commenter's name and affiliation following the comment.

This rule proposal can be viewed or downloaded from the Department's website at <http://www.state.nj.us.dep>.

The agency proposal follows:

Summary

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement under N.J.A.C. 1:30-3.3(a)5.

The Department is proposing to readopt without amendments the Regulations Governing the Certification of Laboratories and Environmental Measurements at N.J.A.C. 7:18. In accordance with the "sunset" provisions of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., the Regulations Governing the Certification of Laboratories and Environmental Measurements were due to expire on June 11, 2006. The expiration date has been extended by 180 days to December 8, 2006 pursuant to N.J.S.A. 52:14B-5.1c.

N.J.A.C. 7:18 governs the certification of and the procedures used by laboratories that conduct analytical testing for many of the Department's regulatory programs. The laboratory certification program is an essential part of the Department's mission. Much of the Department's permit, site remediation, enforcement, research, and technical programs depend on obtaining reliable, accurate, precise, and high quality data regarding samples of drinking water, groundwater, wastewater, air, soils, solid waste, hazardous waste, and sludge. The laboratories providing this data therefore must be depended upon to meet quality assurance and quality control requirements. The purpose of the laboratory certification program is to ensure that dependability. New Jersey businesses, residents and the Department all benefit as a result.

Under the laboratory certification program, results of testing and analysis can be accepted to establish compliance with the Department's rules only if the testing or analysis is performed by an environmental laboratory certified by the Department. To obtain and maintain its certification, a laboratory must meet the standards set forth in these rules.

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The standards govern laboratory facilities, personnel, equipment and instrument calibration and maintenance, quality assurance/quality control, laboratory records, data reporting and maintenance, and other laboratory practices. The Department evaluates compliance with these standards through on-site audits of environmental laboratories. The Department uses a proficiency testing program to evaluate a laboratory's performance in analyzing samples that contain known concentrations of specific parameters.

Through these rules, the Department offers laboratories a choice of certification through the New Jersey Environmental Laboratory Certification Program pursuant to N.J.A.C. 7:18 or the National Environmental Laboratory Accreditation Program (NELAP) pursuant to the National Environmental Laboratory Accreditation Conference (NELAC) standards, incorporated by reference at N.J.A.C. 7:18-1.5(d). The following is a summary of the rules proposed for readoption.

Subchapter 1, General Provisions, contains general provisions describing the scope, purposes and basic requirements of the laboratory certification program, and includes definitions of terms used in N.J.A.C. 7:18 and other aids to construction.

The rules proposed for readoption cover laboratories performing sample analyses required to demonstrate compliance with certain statutes, and with rules and orders issued under the authority of those statutes. The statutes include the Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq.; the Water Pollution Control Act, N.J.S.A. 58:10A-1 et seq.; the radon provisions of the Radiation Protection Act, N.J.S.A. 26:2D-70 et seq.; the Solid Waste Management Act, N.J.S.A. 13:1E-1 et seq.; the Industrial Site Recovery Act, N.J.S.A. 13:1K-6 et seq.; the Spill Compensation and Control Act, N.J.S.A. 58:10-23.11 et seq.; the Private Well Testing Act, N.J.S.A. 58:12A-26 et seq.; and the Air Pollution Control Act, N.J.S.A. 26:2C-1 et seq. The rules establish procedures and criteria for the affected laboratories to obtain and maintain certifications, and the requirements they must follow in their work with environmental samples.

Subchapter 2, Program Procedures and Requirements, establishes procedures and requirements for the laboratory certification program. This subchapter outlines the work that certified environmental laboratories can perform, and prohibits other persons from performing this work. It outlines the procedure for becoming a certified environmental laboratory; requirements that a laboratory must meet to become and remain a certified environmental

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laboratory; procedures for modifying, suspending or revoking a certification; and the test methods and procedures available for certification.

A certified laboratory is authorized to use only certain specified methods in analyzing samples. The laboratory cannot use other methods for the purpose of establishing compliance with regulatory programs. This subchapter also describes the categories for certification. In the application, the applicant must specify the areas for which it is seeking certification. A laboratory can become certified in any or all of the regulatory programs covered by N.J.A.C. 7:18, including the Safe Drinking Water Program, the Water Pollution Program, the Radon/Radon Progeny-in-air Program, the Solid/Hazardous Waste Program, the CERCLA (CLP) Program and the Clean Air Program.

When the Department certifies an applicant as a certified environmental laboratory, it will issue two documents to the laboratory: a certificate, and an "Annual Certified Parameter List" (ACPL). The certificate documents the applicant's status as a certified environmental laboratory. The ACPL shows the scope of the laboratory's authorization to analyze samples. The ACPL lists the regulatory programs with which the laboratory's analyses can demonstrate compliance; the analytical techniques and methods that the laboratory can use; and the specific parameters or groups of parameters that the laboratory can analyze. The ACPLs issued by the Department also include category codes for each parameter, technique and method for which the laboratory is certified. A certified environmental laboratory is authorized to perform analyses and report results to the Department only as specified in its ACPL.

The laboratory certification program includes twenty-eight categories of parameters within the regulatory programs listed above. A parameter is a contaminant, constituent, or substance present in a sample, or a characteristic of a sample. The Safe Drinking Water Program includes seven categories of parameters; the Water Pollution Program includes eight categories; the Radon/Radon Progeny Program includes one category; the Solid/Hazardous Waste Programs include eleven categories; the CERCLA (CLP) Program includes two categories, and the Clean Air Program includes four categories. A laboratory may analyze samples for only the parameters specified in the certification and ACPL. The ACPL will also specify the analytical technique and method for the parameter.

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A technique is the instrumental or manual procedure that a laboratory uses to analyze a sample. One or more techniques may be available to analyze a sample for a given parameter. A laboratory may use only the technique or techniques for which it is certified.

A method is a specified procedure for using a given technique. For each technique, a laboratory must use only the method for which it is certified.

The methods that a laboratory may become certified to use are known as "Department-Sanctioned Analytical Methods," or "DSAMs." Currently, all DSAMs are set forth in rules or other documents that have been incorporated into the rules proposed for re-adoption by reference. The sources of these DSAMs include the "National Primary and Secondary Drinking Water Regulations," 40 C.F.R. 141 and 40 C.F.R. 143; the "Guidelines Establishing Test Procedures for the Analysis of Pollutants," 40 C.F.R. 136; the methods listed in Subchapter 1, Solid Waste, 40 C.F.R. 260, 261; CERCLA (CLP) Program methods, listed in Invitation for Bid (Bid) documents published in the Commerce Business Daily; the United States Environmental Protection Agency (USEPA) methods for air testing, and the Department's analytical methods for sludge analysis.

Subchapter 2 also establishes the fees for the laboratory to obtain or maintain certification. The fee includes two components. The administrative component covers the costs common to all applications of a given type. This fee is the same for all applications. The second component of the fee depends upon the parameters for which the applicant is seeking certification. The schedule for payment of fees reflects the "certification year" that begins on July 1 of each year and ends on June 30 of the following year.

Subchapter 3, General Requirements for Facilities, Equipment and Safety, contains general requirements for facilities, equipment and safety. These general requirements are in addition to the more specific requirements of N.J.A.C.7:18-4 through 8, which apply to specific types of analyses.

Subchapters 4 through 8 apply to certified environmental laboratories, and to laboratories analyzing proficiency testing samples for the purpose of becoming certified. Each subchapter establishes requirements for equipment, instruments, supplies and materials used in the specified type of testing, as well as requirements for a quality assurance/quality control program that apply to testing in specified categories of parameters. If a laboratory failed to follow these requirements, the quality of its data would be suspect. Each subchapter directs laboratories to

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satisfy the requirements of subchapters 1 through 3, and the requirements of any applicable DSAM. The requirements of a DSAM may be more stringent than the requirements of the rule; in that case, the laboratory must satisfy the more stringent requirement of the DSAM.

The laboratory is also required to develop and implement a written methods manual containing standard operating procedures for each DSAM for which it is certified. The laboratory is required to keep copies of the methods manual in a location convenient to personnel performing analyses and related procedures. Subchapters 4 through 8 each establish recordkeeping requirements and requirements for reporting of data.

Subchapter 4, Microbiological Testing, establishes requirements for microbiological testing of regulatory samples for the Safe Drinking Water Program, the Water Pollution Program, and the Solid/Hazardous Waste Program.

Subchapter 5, Chemical Testing, establishes requirements for laboratories performing chemical testing of regulatory samples for the Safe Drinking Water Program, the Water Pollution Program, the Solid/Hazardous Waste Program, the CERCLA (CLP) Program and the Clean Air Program.

Subchapter 6, Radiochemical Testing Procedures Including Radon Gas/Radon Progeny, establishes requirements for laboratories performing radiochemical testing and radon/radon progeny-in-air testing of regulatory samples for drinking water, water pollution and radon/radon progeny-in-air parameters. Specifically, the subchapter applies to radiochemical testing of regulatory samples in drinking water, wastewater and radon in air.

Subchapter 7, Acute Toxicity Testing, establishes requirements for laboratories performing acute toxicity testing. This subchapter also incorporates required methods for acute toxicity testing.

Subchapter 8, Analyze Immediately Environmental Measurements, establishes requirements for time sensitive regulatory samples for the Safe Drinking Water Program, the Water Pollution Program, the Solid/Hazardous Waste, and the Clean Air Program. The analyze-immediately categories include parameters for which Federal regulations (or methods incorporated by reference into those regulations) require a holding time of analyze-immediately, or state that no storage is allowed. Examples of these parameters include chlorine, total residual; hydrogen ion (pH); oxygen, dissolved (probe); sulfite; and temperature. Analysis for these parameters in an off-site laboratory hours or days after sampling will give invalid results.

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Therefore, analyses must be performed immediately after sampling, either in the field, in an on-site mobile laboratory, or facility laboratory, such as at a wastewater treatment plant.

Subchapter 9, Sample Requirements, establishes requirements for the handling and preservation of regulatory samples for microbiological, inorganic, organic, radiochemical, and acute toxicity testing. The subchapter also establishes requirements for sample collection; these requirements apply to samples for acute toxicity testing only.

When the laboratory is handling or preserving regulatory samples (or collecting regulatory samples for acute toxicity testing), it must satisfy the requirements of this subchapter. In many cases, however, the laboratory will be accepting samples for analysis that have been collected by other persons. In such cases, the laboratory must verify that the samples have been handled and preserved (and collected, if the laboratory will be performing acute toxicity testing) in accordance with this subchapter. Whether it is the laboratory or another person who collected the sample, the laboratory cannot submit results of the analysis for regulatory purposes unless it verifies that the requirements of this subchapter were satisfied.

Subchapter 10, Civil Administrative Penalties and Administrative Orders, establishes procedures for enforcement actions taken for violations of the laboratory certification rules, and for violations of orders issued pursuant to the rules. When a violation arises in connection with a particular program (for example, drinking water, water pollution, solid/hazardous waste), the available enforcement remedies are based upon and authorized by the statute that establishes the program in question. As with any certification program, serious or repeated violations of these rules may result in suspension or revocation of certification. The grounds for suspension or revocation are set forth in subchapter 2.

Social Impact

The Department anticipates that the rules proposed for readoption will continue to have a positive social impact as they are an essential part of the Department's efforts to protect public health and the environment. Many of the Department's programs that protect public health and the environment depend on obtaining reliable, accurate, precise and high-quality data regarding the analysis of samples. The rules proposed for readoption will continue to protect the public from unqualified or unscrupulous laboratories that are more likely to provide inaccurate or false results on samples. At the same time, qualified laboratories that meet the standards in the rules

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proposed for readoption will continue to not be at a disadvantage to less qualified or scrupulous laboratories.

Economic Impact

The Department anticipates that the rules proposed for readoption will continue to have a positive economic impact. These impacts arise from the cost savings from maintaining an effective Laboratory Certification Program. The rules proposed for readoption ensure the quality and reliability of the analytical data used by the Department and New Jersey citizens. As a result, there is less of a need to reject environmental analytical data because of improper or inadequate analytical techniques or procedures, so that more funds used to support environmental analyses will be spent to obtain valid analytical data. The rules proposed for readoption will also continue to help ensure that the environmental decision-making processes, which cost both the regulating agencies and the regulated community significant amounts of money each year, are based on accurate data. When inaccurate data are used for compliance, the money spent on compliance efforts may be wasted.

The fee structure in the rules was developed in 1995 and was revised in 2003 to include the addition of the Clean Air Program Categories CAP01-CAP04. The Department intends to review the fee requirements in State Fiscal Year 2007, in consultation with the Environmental Laboratory Advisory Committee.

The Department anticipates that the economic impact of the rules proposed for readoption will continue to depend on the categories in which a participating laboratory is certified. The fees for laboratories vary depending on the diversity and number of analytical methods performed. To apply for certification, a laboratory must prepare an application and submit it to the Department. The application includes basic information to identify the applicant, its principals and its key employees and their qualifications. Accordingly, the laboratory should be able to complete the application without assistance from consultants or other professionals, and should be able to do so at a nominal cost.

With regard to other costs associated with meeting certification requirements, costs are incurred in several areas including equipment, personnel, penalties, sample handling and preservation, record keeping, and quality assurance. The rules proposed for readoption will continue to maintain all of the existing requirements in these areas. Therefore, there will be no

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increased cost to laboratories maintaining the same certification under the rules proposed for readoption. A laboratory obtaining certification for the first time under the rules proposed for readoption would incur costs in these areas. However, it is important to note that the analysis of samples to demonstrate compliance with the Department's regulatory programs is normally only a small part of a certified laboratory's business. All environmental laboratories require the same equipment, instruments and materials to perform similar analyses for other organizations or the public. The requirements for these items are primarily established by the analytical methods incorporated by reference. Accordingly, laboratories following the accepted methods will need this equipment, instruments and materials whether or not they seek to become certified under the rules.

The rules proposed for readoption establish requirements to ensure that laboratory personnel have sufficient education, training and experience. Persons with these qualifications are likely to command higher compensation than unqualified personnel. Accordingly, a laboratory that lacks qualified personnel would most likely incur additional personnel costs in becoming certified. However, for the same reasons discussed above regarding equipment, the Department expects that laboratory staff already meet the qualification requirements of the rules proposed for readoption, making additional personnel expenditures unlikely.

Environmental Impact

The Department anticipates that the rules proposed for readoption will continue to have a beneficial environmental impact. The Department's permit, site remediation, enforcement, research, and technical programs depend on obtaining reliable, accurate, precise, and high-quality data regarding samples of drinking water, groundwater, wastewater, air, soils, solid waste, hazardous waste, and sludge. The Department anticipates that the rules proposed for readoption will continue to help ensure that the Department obtains data that meets these standards.

Federal Standards Statement

Executive Order No. 27(1994) and N.J.S.A 52:14B-1 et seq. require that administrative agencies which adopt, readopt, or amend State regulations that exceed any Federal standards or

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requirements include in the rulemaking document a comparison with Federal law. The rules proposed for readoption incorporate regulations promulgated by the USEPA, including:

- The “National Primary And Secondary Drinking Water Regulations,” 40 C.F.R. 141 and 40 C.F.R. 143;
- The “Guidelines Establishing Test Procedures for the Analysis of Pollutants,” 40 C.F.R. 136; and
- The methods listed in Subchapter 1, Solid Waste, 40 C.F.R. 260, 261.

The Department also incorporates Federal methods for the CERCLA (CLP) Program into the rules. These methods are published in the Commerce Business Daily.

The USEPA has issued guidance documents and other publications addressing the analysis of environmental samples, which also have been incorporated by reference into the rules.

For some types of analyses covered by the rules proposed for readoption, the USEPA has not promulgated regulations or published guidance. However, nationally recognized technical organizations (such as the American Society for Testing Materials, the American Public Health Association, and the United States Geological Survey) have published manuals or other guidance that includes methods for these types of analyses. The Federal government has recommended the use of such methods, and the Department has incorporated them into N.J.A.C. 7:18 by reference. The Department’s analytical methods for sludge analyses, located at N.J.A.C. 7:14C, are also drawn from these sources as well.

The rules proposed for readoption establish a certification program for laboratories performing environmental analyses, and establish the administrative procedures to be followed by certified environmental laboratories and by laboratories seeking to become certified environmental laboratories. The Federal government does not administer a corresponding program and has no law that corresponds to this aspect of the rules. However, the USEPA is a sponsor of the National Environmental Laboratory Accreditation Conference (NELAC) standards. At 64 F.R. 67450, December 1, 1999, the USEPA stated that NELAC standards can be an alternative means to implement regulatory requirements for drinking water laboratory certification, but they are not a substitute for drinking water regulations. The USEPA strongly encouraged states to adopt NELAC standards, but clearly stated that adoption is voluntary. The Department incorporates by reference the NELAC standards at N.J.A.C. 7:18-1.5(d).

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As discussed above, the rules proposed for readoption do not impose any standards or requirements which exceed the standards or requirements imposed by any applicable Federal law. Accordingly, a Federal standards analysis is unnecessary.

Jobs Impact

The rules proposed for readoption do not materially affect the resources needed by the laboratories that elect to comply with N.J.A.C. 7:18. The Department anticipates that the rules proposed for readoption will not have any impact upon either the creation or loss of jobs in this State.

Agricultural Industry Impact

Pursuant to N.J.S.A. 52:14B-4(a)2, the Department has evaluated this rulemaking to determine the nature and extent of the impact of the rules proposed for readoption on the agricultural industry. The Department anticipates that the rules proposed for readoption will not have an impact upon agriculture in New Jersey.

Regulatory Flexibility Analysis

The rules proposed for readoption affect approximately 800 businesses that operate certified environmental laboratories or laboratories that are seeking certification. Most of these businesses are "small businesses" as defined in the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The rules were designed to minimize adverse economic impacts on all affected businesses while continuing to meet the need for accurate, precise and reliable data. The rules establish performance rather than design standards, whenever feasible, for all affected laboratories. Instead of exempting small businesses specifically from any part of the rules, the Department has recognized that the majority of affected laboratories are small businesses. A discussion of the costs imposed on small businesses can be found in the Economic Impact above.

The small businesses affected by the rules proposed for readoption will themselves vary in size. In general, the smallest businesses are the ones that perform a narrow variety of analyses, and require certification in fewer categories than the larger laboratories; as a result, the

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annual fees and other costs that the smaller businesses incur to comply with the rules are less than the costs that the larger laboratories incur. A description of the compliance standards imposed on small businesses can be found in the Summary above.

Smart Growth

Executive Order No. 4 (2002) requires State agencies that adopt, amend or repeal State regulations to include in the rulemaking document a Smart Growth Impact statement that describes the impact of the rules on the achievement of smart growth and implementation of the State Development and Redevelopment Plan (State Plan). The Department has evaluated this rulemaking to determine the nature and extent of the impact of the rules proposed for re adoption on smart growth and the implementation of the State Plan. The rules proposed for re adoption do not involve land use policies or infrastructure development and therefore, will not have any impact on the achievement of smart growth. As to the implementation of the State Plan, the rules are intended to promote and facilitate the reporting of accurate, reliable, and defensible data to the State for the protection of public and environmental health, which is one of the overall goals of the State Plan. Therefore, the Department believes that the rules proposed for re adoption are consistent with the State's achievement of smart growth and implementation of the State Plan.

Full text of the rules proposed for re adoption may be found in the New Jersey Administrative Code at N.J.A.C. 7:18.

Based on consultation with staff, I hereby certify that the above statements, including the comparison with Federal Standards statement, addressing the requirements of Executive Order 27 (1994), permit the public to understand accurately and plainly the purposes and expected consequences of the rules proposed for re adoption. I hereby authorize this proposal.

Date

Lisa P. Jackson, Commissioner